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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,135	12/18/2006	Doris Bell	C 2864 PCT/US	9061

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EXAMINER	
BAEK, BONG-SOOK	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
10/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,135	BELL ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-25* is/are pending in the application.

4a) Of the above claim(s) *18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/18/2006 and 9/27/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 13-25 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Election/Restrictions

Applicants' election of group I, claims 13-17 and 23-25, drawn to a product comprising the cis-9,trans-11 isomer of conjugated linoleic acid, in the reply filed on 9/3/2009 is acknowledged. The election was made without traverse.

Claims 18-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Claims 13-17 and 23-25 are under examination in the instant office action.

Priority

The instant application is a 371 of PCT/EP03/14592 filed on 12/19/2003 and claims benefit of foreign application filed on 7/18/2003. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of foreign application has been submitted on 1/18/2006.

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be 12/19/2003.

Information Disclosure Statement

Signed and initialed copies of the IDS papers filed on 1/18/2006 and 9/27/2007 are enclosed in this action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 11-17 and 23-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by US patent 6,034,132 (Issue date: 3/7/2000).

US patent 6,034,132 teach a method comprising administering a nutritionally effective amount of conjugated linoleic acid (CLA) to a human, wherein the CLA is provided in the form of a free fatty acid in a pill (medicament) or as a component of a prepared food product (nutritional, dietary supplement or functional food) (abstract). It further teaches that the CLA composition is a more purified mixture consisting of predominantly the cis-9, trans-11 and trans-10, cis-12 isomers, or simply the cis-9, trans-11 isomer alone, which are thought to have the most biological activity (column 3, lines 16-21 and column 4, lines 5-7). Also, it discloses that preferably about 1 to 5 grams of CLA is administered per day and most preferably about 1.8 grams per day may be administered (column 4, lines 24-35), wherein the disclosed range falls within the claimed range in the instant claim 25.

Although the prior art is silent about acting against the hypersensitivity of the bronchia recited in claim 14, since the prior art teaches the use of the same composition in the same dosage as the instant invention, the claimed acting against the hypersensitivity of the bronchia necessarily occurs when the composition is administered. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Alternately, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Since the instant invention is directed to a composition, an intended use (i.e. treating inflammatory diseases such as asthma) recited in claims 13-17, does not have a patentable weight. In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the

statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

2. Claims 11-17 and 23-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 2002/009692 (pub date: 2/7/2002).

WO 2002/009692 teach a composition comprising conjugated linoleic acid (CLA) for the attenuation, prevention, and/or management of the metabolic stress/catabolic response, wherein the conjugated linoleic acid is either a pure isomer of octadecadienoic acid, or a mixture of octadecadienoic acid isomers selected from the group consisting of : cis-8, cis-10; cis-8, trans-10; trans-8, cis-10; trans-8, trans- 10; cis-9, cis-11 ; cis-9, trans-11 ; trans-9, cis-11 ; trans-9, trans-11 ; cis-10, cis-12; cis-9, trans-12 ; trans-9, cis-12; trans-10, trans-12 ; cis-11, cis-13; cis-11, trans-13 ; trans-11, cis-13; and trans-11, trans-13 octadecadienoic acid (p2, lines 14-18, p2, line 28-p3, line 7, claims 6 and 18). It further teaches that conjugated linoleic acid minimizes the expression of IL-1, IL-6, TNF-α, and PGE_2 through its modulating effect on specific cytokines and pro-inflammatory prostaglandins (p5, lines 9-13). Also, it teaches that the conjugated linoleic acid will serve to minimize the stimulation and/or propagation of the stress response and this will enhance the general health and well-being as well as improve recovering from conditions initiating metabolic stress such as asthma (p5, lines 15-22). In addition, it teaches that the composition is taken as a dietary supplement or a pharmacological product (medicament) (p7, lines 7-8). Furthermore, it discloses that preferably about 0.5 to 6 grams of CLA is administered per day (p7, lines 1-6).

Although the prior art is silent about acting against the hypersensitivity of the bronchia recited in claim 14, since the prior art teaches the use of the same composition in the same dosage as the instant invention, the claimed acting against the hypersensitivity of the bronchia necessarily occurs when the composition is administered. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Alternately, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-17 and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-14 and 16-17 of copending Application No. 10/553,374. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '374 application and instant claims are drawn to a composition comprising the cis-9, trans-11 isomer of conjugated linoleic acid. Although the instant claims do not recite "an oligomeric proanthocyanidin or a plant extract containing said proanthocyanidin", which is recited in the claims of '374 application, the instant claims recite the open language "comprising", which does not exclude additional unrecited

elements (see MPEP 2111.03). In addition, since the instant invention is directed to a composition, an intended use (i.e. treating inflammatory diseases such as asthma) recited in the instant claims, does not have a patentable weight. In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached on 8:00-5:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
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